REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the rejection of claims.

Please cancel claims 2, 16, 18, 20 and 22 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of these claims in a continuation application.

Applicants have amended claims 3, 7-11, 14-15, 19 and 23. Obvious typographical errors were corrected. Support for the amendments can be found throughout the specification, including at page 43, lines 21-22 and at page 78, line 13. No new matter has been added by the amendments.

Claims 24-29 are new and are supported throughout the specification, including at page 30, lines 14-24; page 32, lines 4-17; page 34, lines 4-26; and page 44.

Applicants acknowledge the Examiner's withdrawal of the rejections under 35 U.S.C. § 101 and the judicially created doctrine of obviousness-type double patenting.

Objections to the Claims

The Examiner objects to claims 9-11 and 14 under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. Claims 3 and 9-11 have been amended to no longer be multiply dependent. The pending claims do not recite a multiple dependent claim that is dependent upon another multiple dependent claim. Thus, Applicants respectfully request withdrawal of this objection to claims 9-11 and 14 and reinstatement of the claims.

The Examiner provisionally objects to claim 20 as being a substantial duplicate of claim 19. While not acquiescing to the rejection and solely to expedite prosecution, Applicants have cancelled claim 20 rendering the rejection moot. Applicants request withdrawal of this rejection.

Objection to the Specification

The Examiner requests clarity in regards to the abbreviations "IGSF" and "IGSF-3". Applicants submit that these abbreviations represent typographical errors and refer to "ISGF" and "ISGF3". The abbreviation is correct at page 66, line 13. Applicants have amended the typographical errors to correct "ISGF" and "ISGF3". In addition, Applicants have amended the

specification so the first recitation of the term establishes the abbreviation for interferon-stimulated gene factor, as the Examiner correctly noted. It was well known at the time of filing that ISGF3 is a transcription complex of three different proteins--Stat1, Stat2, and interferon-stimulated response element (ISRE). Applicants have submitted Petricoin et al., *Mol. Cell Biol.* 16: 1419-1424 (1996) and Horvath et al., *Mol. Cell Biol.* 16: 6957-6964 (1996) to demonstrate that this transcription complex (ISGF3) was known at the time of filing. Applicants request withdrawal of the objection to the specification.

Rejection under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claim 23 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicants have amended claim 23 to recite "ISGF3 complex". As discussed above, it was well known at the time of filing that ISGF3 complex is a complex of three proteins (Stat1, Stat2, and ISRE) that as the complex serve as a transcription factor (*see* Horvath et al. and Petricoin et al.). Applicants respectfully assert that "ISGF3 complex" was well known at the time of filing. In view of this amendment, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, First Paragraph (Enablement)

The Examiner rejects claims 1-3, 5-8, and 15-23 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Applicants respectfully traverse.

To meet the enablement requirement of 35 U.S.C. §112, first paragraph, a specification must contain a sufficient description to enable one skilled in the art to make and use the claimed invention (*See, e.g., Chiron Corp. v. Genentech, Inc.,* 363 F.3d 1247, 1253 (Fed. Cir. 2004); MPEP §2164.01). A specification does not need to explicitly disclose every detail, and may omit what is well known in the art (*In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); MPEP 2164.01). To make and use an invention may require experimentation even if the specification is enabling (*In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984); MPEP §2164.01). The experimentation must not be unduly extensive (*Id.*), however, costly and timely experimentation alone does not

constitute undue experimentation. (*U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988)).

The Examiner rejected claims 1-3, 5-8 and 15-23 with respect to formalities of deposit. Applicants submit claims 2, 16, 18 and 20 have been cancelled rendering the rejection of these claims moot. Applicants submit amendments to the specification and a statement concerning the availability of the deposited hybridomas were already made in an amendment submitted April 25, 2004. Moreover, Applicants will provide a Declaration concerning the deposited antibodies. Thus, Applicants respectfully request withdrawal of the rejection.

The Examiner rejected claims 5-8 and 21-22. The Examiner contends the claims are inconsistent with the biological activity of the antibodies of claim 1. Applicants respectfully traverse.

Applicants submit that they have exemplified at least one antibody that substantially block activity or binding of a Type I interferon to IFNAR2 and does not block the antiviral activity of a second type I interferon. Applicants submit that the antibody 1D3 does not substantially block activity or binding of a Type I interferon to IFNAR2, such as IFNα-2/1 or IFNβ, and does block the activity of a first type I interferon and does not block activity of a second type I interferon. Applicants have also described and exemplified how to make such antibodies and how to test for blocking of binding and/or activity of more than one type I interferon. See the specification, for example, at page 27, lines 6 to page 28, line 26; pages 62-66. Applicants have also deposited the antibody 1D3. Applicants submit that any experimentation required would not be undue experimentation as one of skill in the art could readily follow the examples in the specification to isolate antibodies having the characteristics as claimed.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement.

Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejects claim 3 under 35 U.S.C. § 112, first paragraph, for an alleged lack of written description. Applicants respectfully traverse.

As an initial matter, Applicants note there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *See* Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph "Written Description Requirement" IIA. Furthermore, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by reduction to practice, by disclosure of relevant identifying characteristics such as structure, physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of these characteristics. *MPEP 2163 II. A.3.(a)ii).* When the above factors are carefully weighed, the specification clearly describes the claimed subject matter in a manner reasonably conveying to one of skill in the art that Applicants had possession of the claimed invention.

Claims 3 is directed to a polypeptide comprising a portion of the antibody of claim 1, wherein the portion comprises an antigen binding fragment.

Applicants submit that one of skill in the art reading the specification would understand that Applicants were in possession of the claimed subject matter. Applicants have described antigen binding fragments, such as Fab, Fab', $F(ab')_2$, Fv fragments, diabodies, scFv and multispecific antibodies formed from antibody fragments. See the specification, for example, at pages 7-11 and pages 49-52. Applicants have described polypeptides comprising antigen binding fragments, such as fusion proteins, to at least a portion of viral coat proteins such as used in phage display, as well as antigen binding fragments labeled with biotin, and alkaline phosphatase. See the specification, for example, at page 14, lines 6-15; pages 50-52 and pages 55-58. Applicants submit that many such polypeptides are known to those of skill in the art, such as a bispecific molecule, including a Fab and an immunoadhesin, antibodies labeled with tag peptide useful in purification and detection, and the like. Thus, Applicants submit the specification provides written description for the claimed subject matter.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102(b)

The Examiner rejects claims 1-2, 5-8, and 15-23 under 35 U.S.C. § 102(b) as allegedly being anticipated by *Chuntharapai et al.* (*FASEB Journal*, abstract #1877, 10(6):A1325, April 30, 1996), *Novick et al.* (*Cell*, 1994 May 6:77(3):391-400), and *Colamonici et al.* (*J Biol Chem.* 1993 May 25; 268(15):10895-9). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully traverse.

The Examiner rejects claims 1-2, 5-8, and 15-23 under 35 U.S.C. § 102(b) as allegedly being anticipated by *Chuntharapai et al.* (FASEB Journal, abstract #1877, 10(6):A1325). Claims 2, 16, 18 and 20 have been cancelled rendering the rejection of these claims moot. Applicants traverse with regard to the remainder of the claims. Applicants respectfully assert that the cited abstract does not teach or suggest the antibodies as claimed. This abstract does not disclose the characteristics of monoclonal antibodies 1D3, 1F3, and 3B7 as claimed. It is believed that the hybridomas producing the monoclonal antibodies 1D3, 1F3, and 3B7 were not publicly available prior to the filing of U.S. Patent Appl No. 60/061,185, filed October 6, 1997. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

The Examiner rejects claims 2, 16, 18, 19, and 20 under 35 U.S.C. § 102(b) as allegedly being anticipated by *Novick et al.* (Cell. 1994 May 6:77(3):391-400). Applicants have cancelled claims 2, 16, 18, and 20 rendering the rejection of these claims moot. Claim 19 has been amended to recite an anti-IFNAR2 antibody 1D3 produced by a hybridoma cell line with ATCC Accession No. HB 12428. Thus, this rejection is now moot. Applicants respectfully request removal of this rejection.

The Examiner rejects claims 2, 16, 18, 19, and 20 under 35 U.S.C. § 102(b) as allegedly being anticipated by *Colamonici et al.* (J Biol Chem. 1993 May 25; 268(15):10895-9). Applicants have cancelled claims 2, 16, 18, and 20 rendering the rejection of these claims moot. Claim 19 has been amended to recite an anti-IFNAR2 antibody 1D3 produced by a hybridoma cell line with ATCC Accession No. HB 12428. Thus, this rejection is now moot. Applicants respectfully request removal of this rejection.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b).

Rejections under 35 U.S.C. § 103(a)

The Examiner rejects claims 1-3, 5-8, and 15-23 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Chuntharapai et al.* (FASEB Journal, abstract #1877, 10(6):A1325, April 30, 1996) in view of U.S. Patent No. 6,458,932 (Novick et al.) and claims 2-3, 16, and 18-20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Novick et al.* (Cell. 1994 May 6:77(3):391-400), or *Colamonici et al.* (J Biol Chem. 1993 May 25;268(15):10895-9) in view of U.S. Patent No. 6,458,932 (Novick et al.). Claims 2, 16, 18, 20 and 22 have been cancelled rendering the rejection of these claims moot. Applicants respectfully traverse these rejections.

To establish a *prima facie* case of obviousness, three criteria must be met--a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

(1) The Examiner rejects claims 1-3, 5-8, and 15-23 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Chuntharapai et al.* (FASEB Journal, abstract #1877, 10(6):A1325, April 30, 1996) in view of U.S. Patent No. 6,458,932 (Novick et al.). Applicants respectfully traverse this rejection with respect to claims 1, 3, 5-8, 15, 17, 19, 21 and 23.

The Examiner has not established a *prima facie* case of obviousness since the combination of the two cited references do not describe or teach all of the elements of the claims. As discussed above, the Churuntharapai abstract is not an enabling reference and does not teach or suggest the characteristics of the anti-IFNAR2 antibodies as claimed. The Churuntharapai abstract does not disclose the characteristics or public availability of the antibodies or the hybridomas that produce the claimed antibodies. The Novick patent does not remedy this deficiency as the Novick patent does not teach or suggest that anit-IFNAR2 antibodies can or should be made that do not substantially block the binding of a type I interferon. Thus, the cited references do not teach or describe all of the elements of the claims.

The Examiner's argument asserts that a person skilled in the art could have arrived at the monoclonal antibodies 1D3, 1F3, and 3D7 based on the methods taught in the abstract and the

Novick patent. Applicants further submit with respect to claims 5-8 that the Novick et al. reference does not teach or suggest that an antibody that binds to IFNAR2 can or should be made that does not substantially block the binding or an antiviral activity of a type I interferon. The antibodies of Novick et al. were not characterized in the patent. Thus, Applicants submit that the references even when combined do not disclose all of the elements of the claims.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

(2) The Examiner rejects claims 2, 3, 16, 18, 19, and 20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Novick et al.* (Cell. 1994 May 6:77(3):391-400), or *Colamonici et al.* (J Biol Chem. 1993 May 25;268(15):10895-9) in view of U.S. Patent No. 6,458,932 (Novick et al.). Applicants have cancelled claims 2, 16, 18, and 20 rendering the rejection of these claims moot. Claim 3 has been amended to depend upon claim 1. Claim 19 has been amended to recite an anti-IFNAR2 antibody 1D3 produced by a hybridoma cell line with ATCC Accession No. HB 12428. Applicants respectfully assert that this rejection is now moot since claims 2, 16, 18, and 20 have been cancelled and it is not applicable to amended claims 3 and 19. Applicants respectfully request removal of this rejection.

Request for an Interview

Applicants request an interview with the Examiner and his supervisor upon receipt of these papers.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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